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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------|
| 10/681,669   | 10/07/2003  | Arthur J. Blume      | 2598-4000US4             | 7579             |
| 27123  | 7590        | 10/04/2005           | EXAMINER                 |                  |
| MORGAN & FINNEGAN, L.L.P.<br>3 WORLD FINANCIAL CENTER<br>NEW YORK, NY 10281-2101 |             |                      | TUNGATURTHI, PARITHOSH K |                  |
|  |             |                      | ART UNIT                 | PAPER NUMBER     |
|  |             |                      | 1643                     |                  |

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                     |  |
|------------------------------|--------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |  |
|                              | 10/681,669               | BLUME, ARTHUR J.    |  |
|                              | <b>Examiner</b>          | <b>Art Unit</b>     |  |
|                              | Parithosh K. Tungaturthi | 1643                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

*Handwritten mark*

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24, drawn to a method of identifying a ligand capable of binding to at least one determinant of a biologically active site on a target, which determinant participates in conferring biological activity of said target, classified in class 435, subclass 7.1 for example.
  - II. Claims 25-46, drawn to a method of identifying ligands capable of binding to at least two determinants which together are required for biological activity of a pharmacological target, classified in class 435, subclass 7.1 for example.
  - III. Claims 47-50, drawn to a reporter, classified in class 530, subclass 387.1+.
  - IV. Claims 51-54, drawn to a method wherein two peptides are attached to the rVab component to form rVab-Pep<sup>2</sup>, classified in class 435, subclass 7.1, for example
  - V. Claims 55-59, drawn to a method of identifying a ligand capable of binding to at least one determinant of a biologically active site on a target, which target requires activation of at least two determinants to express biological activity of said target, classified in class 435, subclass 7.1 for example..

- VI. Claims 60-74, drawn to a recombinant rVab antibody library comprising rVab members possessing at least one VL and VH region derived from a parental variable region with at least one CDR which is diversified to form different rVab members by deleting, inserting or substituting at least one amino acid within at least one CDR, classified in class 435, subclass 69.6.
  - VII. Claim 75, drawn to a method of providing a model for a ligand capable of binding to a determinant of an active site of a pharmacological target, classified in class 435, subclass 7.1, for example.
2. The inventions are distinct, each from the other because of the following reasons:
- Inventions of Groups III and VI represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The reporter molecule of Group III and the antibody of Group VI are structurally and chemically different from each other. The reporter molecule is made by translation of mRNA for example and the antibody is raised by immunization. Furthermore, the reporter molecule can be used to modify the expression of a protein product and the antibody can be used to immunopurify the polypeptide, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions III and VI are patentably distinct.

The inventions of Groups I, II, IV, V and VII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Group I recites a method of identifying a ligand capable of binding to at least one determinant of a biologically active site on a target, which determinant participates in conferring biological activity of said target, Group II a method of identifying ligands capable of binding to at least two determinants which together are required for biological activity of a pharmacological target, Group IV recites a method wherein two peptides are attached to the rVab component to form rVab-Pep<sup>2</sup>, Group V recites a method of identifying a ligand capable of binding to at least one determinant of a biologically active site on a target, which target requires activation of at least two determinants to express biological activity of said target, Group VII recites a method of providing a model for a ligand capable of binding to a determinant of an active site of a pharmacological target, classified in class, subclass. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I,

II, IV, V and VII are separate and distinct in having different method steps and different endpoints and are patentably distinct.

The inventions of Group III and the method of Groups I, II, IV, V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography in addition to the materially different methods of Groups I, II, IV, V and VII.

***Election of species within Group I***

3. This application contains claims directed to the following patentably distinct species of the claimed invention I

If group I is elected, the applicant is required to elect

One species from the following list:

Species a) polypeptide

Species b) protein

Species c) nucleic acid

Species d) oligosaccharide

Species e) carbohydrate

Species f) lipid

**AND**

One species from the following list:

Species g) detectable free radical

Species h) fluorescent or chemiluminescent group

Species i) radioactive isotope

Species j) oligomerization

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-14, 16, 17 and 19-24 are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in their structure and function.

***Election of species within Group II***

4. This application contains claims directed to the following patentably distinct species of the claimed invention II

If group II is elected, the applicant is required to elect one species from the following list:

Species a) detectable free radical

Species b) fluorescent or chemiluminescent group

Species c) radioactive isotope

Species d) oligomerization

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 25-35 and 37-46 are generic.

The species discussed above patentably distinct because of their distinct properties including the differences in their structure and function.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.



6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

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found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
Parithosh K. Tungaturthi, Ph.D.  
Ph: (571) 272-8789



**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**